

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
NORTHERN DIVISION

SHANNON LAPORTE, et al.,

Plaintiffs,

v.

ROBERT GORDON, DR.
SANDIP SHAH, DR. SARAH
LYON-CALLO, MARY
KLEYN, AND MARY SEETERLIN,
in their official capacities,

Defendants.

Case No. 20-10089

Hon. Thomas L. Ludington
Magistrate Patricia T. Morris

**OPINION AND ORDER DENYING PLAINTIFFS' MOTION FOR PRELIMINARY
INJUNCTION**

All 50 states have newborn screening programs for at least 29 health conditions. NIH, *How Many Newborns are Screened in the United States?*, <https://www.nichd.nih.gov/health/topics/newborn/conditioninfo/infants-screened#f3> (last reviewed 9/1/2017). The screening process is begun by withdrawing a few drops of blood from a baby's heel 24 to 36 hours after a child's birth. *50th Anniversary, 1965-2015 Michigan Newborn Screening: A Public Health Success Story*, https://www.michigan.gov/documents/mdch/Newborn_Screening_Book_500007_7.pdf. Five or six spots of the blood are maintained on a filter paper card and then sent to the State Newborn Screening Laboratory for testing. *Id.* The child's primary medical care provider is informed immediately of any adverse health test result. CDC data show that nationally about 12,500 newborns each year are diagnosed with a condition identified through the newborn screening program. *How Many Newborns are Screened in the United States?* "Approximately 6.9 million Michigan newborns have been screened with more than 7,200 babies identified with disease and treated early for disabling and life threatening conditions." *50th Anniversary*.

MCL § 333.5431 was added to the Michigan public health code in 1978 as part of a comprehensive reform to the code. House Legislative Analysis, *HB 4070* (March 21, 1977). The House Fiscal Agency analysis explains that “[p]rovisions are included which would govern the classification of diseases and disabilities, reporting and surveillance, and procedures for the investigation and control of diseases and disabilities.” *Id.* Initially, the section required a health professional responsible for assistance in the delivery of the child to test infants for “phenylketonuria and other handicapping conditions” under penalty of a misdemeanor. Public Act 368 of 1978.

Over the years the statute was amended, expanding the number of diseases that would be tested by a health professional to more than 50 disorders, adding reporting requirements, and requiring the department to promulgate rules related to the testing. Public Act 300 of 1986; Public Act 14 of 1987; *Senate Fiscal Agency*, Senate Analysis Section SB 162 (April 14, 1987); Public Act 264 of 1988; Public Act 81 of 1992; Public Act 88 of 1998; Public Act 138 of 1999; Public Act 691 of 2002. In 2000, the legislature added language requiring the department to “develop a schedule for the retention and disposal of the blood specimens used for the tests after the tests are completed” and allowing the samples to be used for medical research. Public Act 33 of 2000.

MCL § 333.5431 currently provides in part,

(1) A health professional in charge of the care of a newborn infant or, if none, the health professional in charge at the birth of an infant shall administer or cause to be administered to the infant a test for each of the following:


- (a) Phenylketonuria.
- (b) Galactosemia.
- (c) Hypothyroidism.
- (d) Maple syrup urine disease.
- (e) Biotinidase deficiency.
- (f) Sickle cell anemia.
- (g) Congenital adrenal hyperplasia.
- (h) Medium-chain acyl-coenzyme A dehydrogenase deficiency.

- (i) Other treatable but otherwise disabling conditions as designated by the department.
- (2) The informed consent requirements of sections 17020 and 17520 do not apply to the tests required under subsection (1). The tests required under subsection (1) shall be administered and reported within a time and under conditions prescribed by the department. The department may require that the tests be performed by the department.

The parent or legal representative of a newborn child decides whether all remaining blood samples should be destroyed, only blood samples stored for research should be destroyed, or the blood spots may be stored but not used for research purposes. ECF No. 15-4 at PageID.182.

The opt-in and opt-out processes (depending on an individual's date of birth) are explained on the Michigan Department of Health and Human Services website as well as pamphlets distributed by the department. ECF No. 15-6; 15-8. In short, at birth, a parent or legal guardian decides whether a child's blood spots may be used for research purposes. See the form below.

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 Before you sign this form please read, *Your Baby's Blood Spots*. It explains in more detail how your baby's blood spots may be used in health research through the Michigan BioTrust for Health. If you still have questions, please call the Michigan Department of Health and Human Services (MDHHS) toll free at 1-866-673-9939.


☐ **Yes, my baby's blood spots may be used for health research through the BioTrust.**
By checking this box you understand:

- Unused blood spots are stored using a code and not your child's name. The spots are stored forever at a secure site (Biobank) unless you, or your grown child, change your mind.
- Stored blood spots may be used by the state lab to help ensure that newborn screening detects those at risk. Stored blood spots may also be used for research approved by MDHHS. Blood spots can only be used for studies to better understand disease or improve the public's health.
- Many types of laboratory methods are used to study biological factors like DNA or environmental factors like metals and toxins.
- The risk for using your baby's blood spots in research is that it could be identified. This risk is very low. Many steps are taken to protect privacy. Details that could identify your child or family are removed before your child's blood spots are given to a researcher.
- Most likely you or your child will not benefit from blood spot research.
- Participation is voluntary. You can call MDHHS at any time if you change your mind. There is no penalty or loss of benefits for saying no or changing your mind.

☐ **No, my baby's blood spots may not be used for health research.**
By checking this box you understand:

- Blood spots will be stored forever but not used for research. These stored blood spots may still be used by the state lab to help ensure that newborn screening detects those at risk.
- You must contact MDHHS if you do not want blood spots stored for any reason after newborn screening.

 MDHHS Copy
2097001

 38371

Parent Signature

Date

Your choice applies to all blood spots collected for newborn screening. Please visit www.michigan.gov/biotrust for further information including research updates. For questions about your research rights or whom to contact in case of a research-related injury, please call the MDHHS IRB at 517-241-1928.

If the parent wants to amend their response and/or have the blood spot destroyed, the following form is used later.

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RESIDUAL NEWBORN SCREENING BLOOD SPOT DIRECTIVE

Michigan Department of Health and Human Services

Child's Name at Birth		Date of Birth	
Child's Current Name		Check Birth Order if Multiple Birth <input type="checkbox"/> 1 st <input type="checkbox"/> 2 nd <input type="checkbox"/> 3 rd <input type="checkbox"/> 4 th <input type="checkbox"/> 5 th	
Mother's Name at Time of Child's Birth		Hospital of Birth	
<p>I am a legal representative* of the child named above. I am asking the Michigan Department of Health and Human Services (MDHHS) to (check one):</p> <p><input type="checkbox"/> Destroy all remaining blood spots. I understand that by checking this box, NO blood spots will be available for any future use including medical, identification, or research purposes.</p> <p><input type="checkbox"/> Destroy only the portion of blood spots stored for research use. I understand by checking this box, one blood spot will be held by MDHHS. I must direct any potential future use including medical, identification or research purposes.</p> <p><input type="checkbox"/> Store but not use blood spots for research after newborn screening is complete. I understand that the blood spots will be kept by the laboratory but not used for research of any kind unless directed in writing by me.</p> <p>* Legal representative means a parent or guardian of a minor who has authority to act on behalf of the minor or the individual from whom the specimen was collected if 18 years or older or legally emancipated.</p>			
Signature of parent, guardian or other legal representative		Relationship to Child	
Printed Name		Date	
Street Address	City	Zip Code	Phone Number
<p>If you are asking MDHHS to destroy any blood spots, you must also attach a copy of the birth certificate belonging to the person whose blood spots are being destroyed AND the driver's license, state issued identification card or passport of the person who signed above.</p> <p>Return document(s) via: Email: biotrust@michigan.gov Fax: 517-335-9419 or Post Mail: BioTrust Coordinator, NBS Follow-up Program, PO Box 30195, Lansing, MI 48909</p>			

The Michigan Department of Health and Human Services (MDHHS) does not discriminate against any individual or group because of race, religion, age, national origin, color, height, weight, marital status, genetic information, sex, sexual orientation, gender identity or expression, political beliefs or disability.	Authority: Michigan Public Health Code, Act 368 of 1978
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The Michigan BioTrust for Health and Michigan Neonatal Biobank oversee the storage and use of blood spots for research. MDHHS, *Michigan BioTrust for Health*, https://www.michigan.gov/mdhhs/0,5885,7-339-73971_4911_4916_53246---,00.html (last visited 3/18/2020); Wayne State University, *Michigan Neonatal Biobank*, <https://mnb.wayne.edu> (last visited 3/18/2020). “The Michigan Biotrust for Health was established by MDHHS to promote the research use of residual newborn screening dried blood spots while more optimally preserving the specimens, improving parental decision-making opportunities and increasing awareness in the general public. The Michigan Neonatal Biobank (‘Biobank’) is a storage and management facility for the archive of dried blood spot cards.” *Michigan Neonatal Biobank*. Any unused blood spots from the initial testing of the baby are managed by the BioTrust and stored for up to 100 years. MDHHS, *Michigan BioTrust for Health*.

I.

On January 14, 2020, Plaintiff, Shannon LaPorte on behalf of herself and as parent-guardian of her unborn child, B.O., filed a complaint against officials from the Michigan Department of Health and Human Services (“MDHHS”) in their official capacities. ECF No. 1. Plaintiffs do not clearly differentiate the difference between the alleged violations of B.O.’s parent’s rights and B.O.’s rights. The complaint alleges four counts – Count I alleges that MCL § 333.5431(2) violates the Fourth Amendment, Count III alleges MCL § 333.5431(2) violates the Fourteenth Amendment, Count II alleges the extraction and testing of blood spots of newborns through an MDHHS program violates the Fourth Amendment, and Count IV alleges that medical testing of the blood spots without informed consent violates the Fourteenth Amendment. *Id.* Plaintiffs seek injunctive and declaratory relief, as well as attorney fees. ECF No. 1 at PageID.19.

Plaintiffs also filed a motion for preliminary injunction on the same day. ECF No. 3.

Plaintiffs explain their circumstance as follows,

B.O. is set to be born in late April or early May 2020. The wrongs being challenged are set to occur 24-48 hours after the birth of B.O. absent pre-judgment injunctive relief by this Court. The harm will have been done. And there are no monetary damages available to cure the suffered harm due to state sovereign immunity. As such, *a preliminary injunction is hereby sought to prevent Defendants and all those other persons who are in active concert or participation with Defendants (i.e. the conscripted healthcare professionals at local hospitals and all employees and technicians under the direction of Defendants) from extracting, seizing, and testing B.O.'s blood shortly after the birth of B.O. at the hospital for the purpose of exacting and cataloging highly personal and deeply private genetic/medical data.* A preliminary injunction is warranted until such time as a merits decision on this case can be rendered.

ECF No. 3 at PageID.41 (emphasis added).

The briefing on the motion for preliminary injunction only addresses Counts II and IV of the complaint. Accordingly, Counts I and III will not be addressed.

II.

A related case needs to be addressed: *Kanuszewski v. Michigan Department of Health and Human Services*, 18-10472. When *LaPorte v. Gordon* was filed, Plaintiffs flagged *Kanuszewski v. Michigan Department of Health and Human Services* as a possible companion case. ECF No. 1. Judge Roberts agreed and reassigned *LaPorte* to this Court as a companion case. ECF No. 4. Plaintiff LaPorte is a plaintiff in both the current case and in *Kanuszewski*.

A.

On February 8, 2018, Plaintiff LaPorte, along with Adam and Ashley Kanuszewski, and Lynnette Wiegand, individually and as parent-guardians of their minor children, filed suit against the Michigan Department of Health and Human Services, Nick Lyon (the then-Director of MDHHS), the Dr. Sandip Shah (Director of the Bureau of Laboratories), Dr. Sarah Lyon-Callo (state epidemiologist), Mary Kleyn (Manager of the Newborn Screening Section), Michigan

Neonatal Biobank, Inc., and Dr. Antonio Yancey (Director of the Michigan Neonatal Biobank). ECF No. 3 in 18-10472.

The complaint alleged Defendants violated Plaintiffs' Fourteenth Amendment rights (substantive due process) by extracting and storing blood spots without sufficient consent (Counts I and II), violated Plaintiffs' Fourth Amendment rights by extracting and testing the blood spots (Count III), and violated Plaintiffs' Fourth Amendment rights by indefinitely storing blood spots (Count IV). ECF No. 26 in 18-10472.

Defendants filed motions to dismiss. ECF Nos. 32, 33, 34 in 18-10472. This Court granted the motions to dismiss on the merits, finding the minor children failed to state a claim as to their substantive due process rights because as minors they are not competent to make medical decisions, but their parents are presumed to be competent (Counts I and II), the parents failed to state a claim as to substantive due process rights because their fundamental right to the care of their children was not violated by the extraction and testing of their children's blood (Counts I and II), the children failed to state a claim that their Fourth Amendment right to be free from an unreasonable search of their blood because it was justified under the special needs doctrine (Count III), and the children failed to state a claim based upon their allegation that the indefinite storage of the blood spots violated their Fourth Amendment rights because Plaintiffs' complaint raised rhetorical concerns that the blood spots may be being misused, but otherwise failed to raise any factual corroboration for their rhetorical concerns. (Count IV). *Kanuszewski v. Mich. Dep't of Health & Human Servs.*, 333 F. Supp. 3d 716, 720–30 (E.D. Mich. 2018).

Plaintiffs appealed and the Sixth Circuit affirmed in part and reversed in part.

B.

The Sixth Circuit divided the issues for attention, addressing Plaintiffs' differing circumstances and thus, their standing and sovereign and qualified immunity.

i.

The Circuit first identified the “two types of constitutional violations alleged (substantive due process and the Fourth Amendment) and two types of Plaintiffs (the parents and the children).” *Kanuszewski v. Mich. Dep’t of Health & Human Servs.*, 927 F.3d 396, 406 (6th Cir. 2019). They explained that under the substantive due process claim, the children alleged a violation of their right to refuse medical treatment and the parents alleged their “own fundamental liberty interest in the care, custody and management of their children.” *Id.* Plaintiffs also alleged the children’s Fourth Amendment rights were violated. Both claims (substantive due process and Fourth Amendment) have three “temporal aspect[s]” – “the *completed* collection of the children’s blood samples, as well as the *ongoing* storage of the samples and the risk of the *future* use of the samples by third parties.” *Id.* at 406–07 (emphasis in original).

ii.

Next, the Circuit analyzed whether Plaintiffs had standing and what relief was available. First, they concluded that the children suffered an injury-in-fact when the blood samples were extracted. However, “[b]ecause the blood samples have already been collected, the children’s Fourth and Fourteenth Amendment claims arising out of the initial drawing of blood both pertain to a completed harm and therefore afford the children standing to seek only damages—not injunctive or declaratory relief—resulting from” the alleged violation of their Fourth and Fourteenth Amendment rights. *Id.* at 407. Second, the Circuit concluded the parents suffered an injury-in-fact when their children’s blood samples were extracted, but it was also a completed

harm, so they are only eligible to receive damages, not injunctive or declaratory relief. *Id.* at 407–08. Third, the Circuit held that “[b]ecause the storage of the blood samples represents an ongoing violation, the children will be able to pursue all three forms of relief, i.e., injunctive, declaratory, and damages, in connection with both their Fourth and Fourteenth Amendment claims.” *Id.* at 408–09. Fourth, the Circuit found that “parents have standing to raise claims for injunctive and declaratory relief and damages based on ongoing injuries and the threat of future injuries resulting from the transfer and storage of their children’s blood samples.” *Id.* at 411–12.

iii.

The Sixth Circuit also discussed the issue of the Defendants’ immunity. As the Sixth Circuit explained in *Kanuszewski*,

State sovereign immunity generally bars damages actions against states from proceeding in federal court. *Maben v. Thelen*, 887 F.3d 252, 270 (6th Cir. 2018). This immunity also generally applies to “state agents and instrumentalities,” *Regents of Univ. of Calif. v. Doe*, 519 U.S. 425, 429, 117 S. Ct. 900, 137 L.Ed.2d 55 (1997), including state officials sued in their official capacities. *Maben*, 887 F.3d at 270. For this reason, Plaintiffs cannot seek damages from MDHHS, the Neonatal Biobank, or any individual Defendant sued in his or her official capacity. *Kanuszewski v. Mich. Dep’t Health & Human Servs.*, at 413 (footnotes omitted).

Additionally, qualified immunity is “an immunity from suit rather than a mere defense to liability.” *Mitchell v. Forsyth*, 472 U.S. 511, 526, (1985). The doctrine protects government officials “from liability for civil damages insofar as their conduct does not violate clearly established statutory or constitutional rights of which a reasonable person would have known.” *Harlow v. Fitzgerald*, 457 U.S. 800, 818, (1982). “Qualified immunity balances two important interests—the need to hold public officials accountable when they exercise power irresponsibly and the need to shield officials from harassment, distraction, and liability when they perform their duties reasonably.” *Pearson v. Callahan*, 555 U.S. 223, 231 (2009). “To be clearly established, a right must be sufficiently clear ‘that every reasonable official would [have understood] that what

he is doing violates that right.” *Reichle v. Howards*, 132 S. Ct. 2088, 2093 (2012). “[E]xisting precedent must have placed the statutory or constitutional question beyond debate.” *Ashcroft v. al-Kidd*, 563 U.S. 731, 741 (2011). Qualified immunity protects “all but the plainly incompetent or those who knowingly violate the law.” *Malley v. Briggs*, 475 U.S. 335, 341 (1986). The relevant inquiry is whether “it would be clear to a reasonable officer that his conduct was unlawful in the situation he confronted.” *Saucier v. Katz*, 533 U.S. 194, 202 (2001).

The Circuit found that the Plaintiff children cannot seek damages against any of the Defendants for their Fourteenth Amendment claims for *collecting the blood samples* because the Defendants are entitled to both state sovereign immunity and qualified immunity. *Id.* at 413. Because the Circuit held that the children could only seek damages for collecting the blood sample under the Fourteenth Amendment, the Sixth Circuit affirmed this Court on standing grounds.¹ Second, the Circuit found the Plaintiff children could not seek damages for their Fourteenth Amendment claims as to *storage of the blood samples* because the Defendants were entitled to both state sovereign immunity and qualified immunity. *Id.* at 416-17. However, they could seek declaratory and injunctive relief. Third, the Circuit concluded that the parents could not seek damages for the Fourteenth Amendment claim for *collecting the blood samples* because again, Defendants were entitled to both state sovereign immunity and qualified immunity. *Id.* at 415-16. Because the Circuit previously concluded that the parents were not eligible for injunctive or declaratory relief, the Sixth Circuit affirmed this Court on standing grounds only concluding that

¹ The Sixth Circuit explained that “State sovereign immunity and qualified immunity therefore bar all of Plaintiffs’ claims alleging that the children’s Fourth Amendment rights were violated when Defendants drew their blood and screened it for diseases, and we decline to exercise our discretion to decide whether these actions actually violated the children’s Fourth Amendment rights. . . . [T]his is a situation where ‘it is plain that a constitutional right is not clearly established but far from obvious whether in fact there is such a right.’ We therefore decline to rule on whether the initial drawing of blood violated the children’s Fourth Amendment rights, and we affirm the district court solely on qualified immunity and state sovereign immunity grounds.” *Kanuszewski v. Mich. Dep’t of Health & Human Servs.*, 927 F.3d 396, 523 (6th Cir. 2019).

the parents could not seek relief for their substantive due process right for extraction of the blood samples.² Fourth, the Circuit decided that parents could only seek injunctive and declaratory relief as to their substantive due process claim for the *ongoing storage of the blood* because damages were prohibited by state sovereign and qualified immunity. *Id.* at 418–19.

As to the children’s Fourth Amendment claims, the Circuit held that the children’s claim for damages for the collection of the blood samples was barred by state sovereign and qualified immunity. *Id.* at 422–23. Because the children lacked standing to obtain injunctive or declaratory relief, the Circuit upheld this Court on standing grounds as to the children’s Fourth Amendment extraction claim. Second, as to the children’s Fourth Amendment claim for the ongoing storage of the blood samples, the Circuit held the Defendants have state sovereign and qualified immunity as to damages, but the children can pursue injunctive and declaratory relief. *Id.* at 423–24.

iv.

The Circuit reached the merits of the case on two issues – the children’s Fourteenth Amendment rights regarding the extraction and storage of the blood samples. It held that “any substantive due process rights related to directing the medical care of children devolve upon the parents or legal guardians of the children, rather than the children themselves.” *Id.* at 414–15. Accordingly, the Circuit affirmed this Court on the merits of the children’s Fourteenth Amendment claims.

² The Sixth Circuit explained that “State sovereign immunity and qualified immunity therefore bar all of Plaintiffs’ claims alleging that the parents’ substantive due process rights were violated when Defendants drew their children’s blood and screened it for diseases, and we decline to exercise our discretion to reach the merits of this issue. . . . [W]e cannot easily say, based on the allegations in the Complaint, that the drawing of the children’s blood ‘do[es] not make out a constitutional violation’ of the parents’ substantive due process right to direct their children’s medical care. The Supreme Court has suggested that we might decline to exercise our jurisdiction in situations where ‘it is plain that a constitutional right is not clearly established but far from obvious whether in fact there is such a right.’ Because this issue presents such a situation, we decline to rule on whether the initial drawing of blood violated the parents’ substantive due process rights, and we affirm the district court’s judgment solely on qualified immunity and state sovereign immunity grounds.” *Kanuszewski v. Mich. Dep’t of Health & Human Servs.*, 927 F.3d 396, 416 (6th Cir. 2019) (citations omitted).

v.

After analyzing Plaintiffs’ standing, their available remedies, and Defendants’ immunity, the Circuit reversed and remanded the two remaining claims concluding that discovery was warranted—the parents’ substantive due process claim for injunctive and declaratory relief for the unconstitutional storage of the blood samples and the children’s Fourth Amendment claim for injunctive and declaratory relief for the unconstitutional storage of the blood samples.

vi.

The Sixth Circuit also included footnotes in its opinion explaining that while the parents’ substantive due process claim for injunctive and declaratory relief as to the extraction of blood and the children’s Fourth Amendment claim as to injunctive and declaratory relief for the extraction of blood are barred because the events had already occurred. However, the Circuit continued, “future plaintiffs may be able to demonstrate a risk of future harm that is ‘concrete, particularized, and actual or imminent’ enough to give them standing to pursue such relief. . . . For example, future plaintiffs might consist of individuals who are pregnant or seeking to become pregnant.” *Id.* at 416 n.10; 423 n.15.

C.

In the instant case, Plaintiff LaPorte explains in her complaint that she is now pregnant with her third child, referred to as B.O., who is due to be born at the end of April/beginning of May 2020. ECF No. 1 at PageID.5. Accordingly, she now seeks the injunctive and declaratory relief denied to her in *Kanuszewski* where she lacked standing.

III.

Some background is provided in Plaintiffs’ complaint and in Defendants’ response to the motion for preliminary injunction.

Plaintiffs allege that

Defendants (or their predecessors) have routinely and unlawfully caused the illegal collection of samples of blood from all or nearly all newborn babies in Michigan at the time of birth and stored those samples or ‘spots’ for purposes of testing and then later indefinitely store at least one sample in a warehouse in Lansing, Michigan under the auspices of a program known as the Michigan BioTrust.

...

At the time of birth of a Michigan infant, a health professional in charge of the care of each newborn infant or at the birth of an infant was conscripted by Defendants to cause a needle or other skin-piercing device to breach the infant’s skin to extract five or six samples of blood, known as blood spots.

...

Defendants, by their actions, commands, and directions, illegally and unlawfully cause the piercing of the skin of Michigan infants for the purpose of extracting a part of an infants’ body for testing in a government laboratory without a warrant signed by a neutral and detached magistrate, consent of the Parents, or lawful authorization under state or federal law.

[] The Infants’ blood spots are seized 24-48 hours post-birth on a filter paper collection device known [as] the Dried Blood Spot (“DBS”) card.

...

None of the diseases tested for are contagious or can otherwise spread by human-to-human contact.

ECF No. 1 at PageID.5-10.

A.

Generally, in determining whether to grant injunctive relief, a court must examine and weigh four factors: “(1) whether the movant has shown a strong likelihood of success on the merits; (2) whether the movant will suffer irreparable harm if the injunction is not issued; (3) whether the issuance of the injunction would cause substantial harm to others; and (4) whether the public interest would be served by issuing the injunction.” *Overstreet v. Lexington–Fayette Urban Cty. Gov’t*, 305 F.3d 566, 573 (6th Cir. 2002); *McPherson v. Mich. High Sch. Athletic Ass’n*, 119 F.3d 453, 459 (6th Cir. 1997). “These factors are not prerequisites, but are factors that are to be balanced against each other.” *Overstreet*, 305 F.3d at 573.

Notwithstanding this balancing approach, however, the likelihood of success and irreparable harm factors predominate. Thus, “[a]lthough no one factor is controlling, a finding that

there is simply no likelihood of success on the merits is usually fatal.” *Gonzales v. Nat’l Bd. of Med. Exam’rs*, 225 F.3d 620, 625 (6th Cir. 2000); *Mich. State AFL–CIO v. Miller*, 103 F.3d 1240, 1249 (6th Cir. 1997) (“While, as a general matter, none of these four factors are given controlling weight, a preliminary injunction issued where there is simply no likelihood of success on the merits must be reversed.”).

Plaintiffs bear the burden of demonstrating their entitlement to a preliminary injunction, and its burden is a heavy one. “A preliminary injunction is an extraordinary remedy which should be granted only if the movant carries his or her burden of proving that the circumstances clearly demand it.” *Overstreet*, 305 F.3d at 573. “[T]he proof required for the plaintiff to obtain a preliminary injunction is much more stringent than the proof required to survive a summary judgment motion.” *Leary v. Daeschner*, 228 F.3d 729, 739 (6th Cir. 2000). Thus, plaintiffs may not merely point to genuine issues of material fact which exist, but must affirmatively demonstrate their entitlement to injunctive relief.

B.

The first element is “whether the movant has shown a strong likelihood of success on the merits.” *Overstreet*, 305 F.3d at 573. The Fourth Amendment claim will be addressed first, followed by the Fourteenth Amendment claim.

i.

Plaintiffs first claim that Defendants violate the Fourth Amendment during the initial extraction of the blood spots from the newborns. ECF No. 1 at PageID.15-16. Plaintiffs allege in their motion for preliminary injunction that the Supreme Court has established that taking blood samples without first obtaining a warrant is a per se unreasonable search without an exception to the warrant requirement. ECF No. 3 at PageID.42-43; *Birchfield v. North Dakota*, 136 S. Ct. 2160,

2173 (2016). Plaintiffs further contend that the testing of the blood spots reveals “highly personal and deeply private genetic/medical information” and is a second violation of the Fourth Amendment. *Id.* Defendants respond that the “heel stick” is not a search and even if it is, it is subject to the special needs doctrine and community caretaker exceptions to the warrant requirement.

This exact issue was previously addressed with the same Plaintiff, in *Kanuszewski v. Michigan Department of Health and Human Services*, 333 F. Supp. 3d 716 (E.D. Mich. 2018). This Court held that “a government mandated blood test that involves a non-consensual invasion of bodily integrity, constitutes a search even if the information derived from that search is not used for law enforcement purposes.” *Id.* at 727. This Court continued to explain that in “special needs cases, courts are tasked with balancing the nature of the intrusion on the individual’s privacy against the promotion of legitimate government interests.” *Id.* In *Dubbs v. Head Start, Inc* the 10th Circuit identified three features that special needs exception cases seem to share,

(1) an exercise of governmental authority distinct from that of mere law enforcement—such as the authority as employer, the *in loco parentis* authority of school officials, or the post-incarceration authority of probation officers; (2) lack of individualized suspicion of wrongdoing, and concomitant lack of individualized stigma based on such suspicion; and (3) an interest in preventing future harm, generally involving the health or safety of the person being searched or of other persons directly touched by that person’s conduct, rather than of deterrence or punishment for past wrongdoing.

336 F.3d 1194, 1213–14 (10th Cir. 2003).

This Court held that “state-mandated blood screening meets all three criteria. The exercise of governmental authority to advance public health is entirely distinct from law enforcement objectives. The mandatory blood screening applies to all infants, and involves no individualized considerations of wrongdoing. The Newborn Screening Program is also designed to protect the health and safety of the infants by facilitating early diagnosis, treatment, and prevention.”

Kanuszewski v. Mich. Dep't of Health & Human Servs., 333 F. Supp. 716, 727 (E.D. Mich. 2018).

This Court also explained how *Kanuszewski* differed from *Dubbs*, including that Defendants are following a statute in this case and that “the nature of the intrusion on Plaintiffs’ privacy is minimal when compared to the state’s interest in protecting infant health.” *Id.* The Court has not been persuaded to the contrary. Accordingly, Plaintiffs are unlikely in this Court’s view of the legal authority to prevail on the merits of their Fourth Amendment claim.

ii.

For Count IV, Plaintiffs argue that it “is well-established that the choice of whether to undertake medical procedures constitutionally belongs to the parent because a competent parent speaks for his or her child in matters of medical decisions.” ECF No. 3 at PageID.44. Plaintiffs cited *Cruzan v. Director, Missouri Department of Health* for the proposition that “the patient generally possesses the right not to consent, that is, to refuse treatment.” 497 U.S. 261, 270 (1990). Plaintiffs argue that until the parents provide informed consent to the testing conducted by Defendants, Defendants are precluded from performing the tests. ECF No. 3 at PageID.45.

Defendants explain that the Sixth Circuit found that the program is subject to strict scrutiny. ECF No. 15 at PageID.158. They highlight several lines from the Sixth Circuit’s opinion where the Court of Appeals explains the doctrine of *parens-patriae* (“parent of the nation”) and the state’s authority to protect against parents harming their children. ECF No. 15 at PageID.158-160. Defendants conclude that

Michigan’s interest in preserving the welfare of children is at its strongest in this case, and the alleged invasion from the initial heel stick and screening is minimal. . . . Given the ‘sparse’ case law on this issue, the strength of the government interest in protecting newborns from insidious diseases, and the minimal invasion of the initial heel stick and screening, Plaintiff has not demonstrated a strong or substantial likelihood of success on the merits of her Fourteenth Amendment claim.
ECF No. 15 at PageID.160.

Again, the issue remains the same as in *Kanuszewski*, with the Circuit’s direction that the issue is to be reviewed applying a strict scrutiny standard. Similar to the Fourth Amendment issue, neither party discussed this Court’s decision in *Kanuszewski v. Michigan Department of Health and Human Services*, 333 F. Supp. 3d 716 (E.D. Mich. 2018). Also like the Fourth Amendment claim, the Sixth Circuit affirmed this Court’s decision on the Fourth Amendment claim on procedural standing grounds and did not address the underlying merits of the claim. This Court discussed that “Supreme Court precedent recognizes ‘two competing values of equal worth: the right of parents to parent and the right of children to safety.’” *Id.* at 721 (quoting *Spiering v. Heineman*, 448 F. Supp. 2d 1129, 1140 (D. Neb. 2006)). Based on the reasoning in *Spiering*, this Court applied rational basis review to the fundamental right because “courts have often assumed that various reasonable restrictions on such rights would be permissible, and that such restrictions need not be judged under the strict [scrutiny] test.” *Id.* (quoting 448 F. Supp. 2d at 1139). The Sixth Circuit concluded that the correct standard of review for parents’ right to the care and custody of their children is strict scrutiny, not rational basis. *Kanuszewski v. Michigan Dep’t of Health & Human Servs.*, 927 F.3d 396, 420 (6th Cir. 2019). However, that does not in this Court’s view increase Plaintiffs’ likelihood to prevail on the merits.

The state tests the blood of newborns to determine if the newborn faces a life-threatening disease. There is Supreme Court precedent that mandatory vaccination laws (if the law contains a medical exemption) are constitutional. *Jacobson v. Massachusetts*, 197 U.S. 11, 38 (1905). Similarly, the Sixth Circuit concluded that it is not a violation of the First Amendment for parents to be required to listen to an explanation about the risks of not vaccinating a child before being able to obtain a religious exception waiver, *Nikolao v. Lyon*, 875 F.3d 310 (6th Cir. 2017). The Supreme Court has explained that “parents generally ‘have the rights, coupled with the high duty,

to recognize and prepare [their children] for additional obligations.’ Surely, this includes a ‘high duty’ to recognize symptoms of illness and to seek and follow medical advice.” *Parham v. J.R.*, 442 U.S. 584, 602 (1979) (citation omitted). However, the Court has also cautioned that while “Parents may be free to become martyrs themselves [] it does not follow they are free, in identical circumstances to make martyrs of their children before they have reached the age of full and legal discretion when they can make that choice for themselves.” *Prince v. Massachusetts*, 321 U.S. 158, 170 (1944). Plaintiffs have not demonstrated they are likely to prevail on the merits of the case. The first prong favors Defendants.

C.

The second part of the preliminary injunction test is “whether the movant will suffer irreparable harm if the injunction is not issued.” *Overstreet v. Lexington–Fayette Urban Cty. Gov’t*, 305 F.3d 566, 573 (6th Cir. 2002). Plaintiffs claim irreparable injury will occur if Defendants do not seek proper consent before performing the initial extraction or medical testing. ECF No. 3 at PageID.48. However, as Defendants assert, that is only true if the initial extraction and medical testing actually violate the Fourth and Fourteenth Amendments. ECF No. 15 at PageID.166-167. As discussed in Section III.B., Plaintiffs are not likely to prevail on the merits of their case. Accordingly, irreparable injury is unlikely to occur if B.O. is subject to the NBS testing process.

D.

The third element of the test is “whether the issuance of the injunction would cause substantial harm to others.” *Overstreet v. Lexington–Fayette Urban Cty. Gov’t*, 305 F.3d 566, 573 (6th Cir. 2002). Plaintiffs argue that no harm to third parties would occur if the injunction were issued because the injunction would apply only to B.O. ECF No. 3 at PageID.49. Defendants argue

that “B.O.’s health is inadequately protected unless he is screened for NBS disorders.” ECF No. 15 at PageID.167. B.O., however, is a party to the litigation and is not therefore “others.” The complaint provides that Shannon LaPorte brings suit as “a resident of Michigan and the parent-guardian and next friend to her third minor child, B.O.” ECF No. 1 at PageID.4. B.O. is not a third party. Additionally, even if B.O. were to be considered “others” under the test, Plaintiff LaPorte admits she is willing to have the test performed in a private lab or by Defendants with her consent, if her doctors recommend it. ECF No. 3 at PageID.49.

On its face, it appears no other parties would be harmed if the preliminary injunction were granted as to B.O. only. However, if a preliminary injunction were granted and then additional parents sought injunctions on behalf of their children, the NBS testing program could be undermined throughout the course of litigation – litigation where Plaintiffs are not likely to prevail on the merits. This potential result favors Defendants. That said, if no other parent seeks to avoid the test meant to assist newborns, the third factor favors Plaintiffs. Accordingly, the third factor does not exclusively favor either Plaintiffs or Defendants.

E.

The fourth factor is “whether the public interest would be served by issuing the injunction.” *Overstreet v. Lexington–Fayette Urban Cty. Gov’t*, 305 F.3d 566, 573 (6th Cir. 2002). Plaintiffs argue that “[t]he public interest is served by having this case resolved on the merits and not unfairly mooted by non-enjoined illegal acts of Defendants. Moreover, it is always in the public’s interest to prevent a violation of an individual’s constitutional rights, which, it is.” ECF No. 3 at PageID.50. Defendants counter that “the public interest favors preserving the health and safety of children, as well as the uniform enforcement of the law.” ECF No. 15 at PageID.169. Defendants also argue Plaintiffs are unlikely to prevail on the merits of their claim, which

undermines their argument that “it is always in the public’s interest to prevent a violation of an individuals’ constitutional rights” when there has not been a constitutional violation. ECF No. 3 at PageID.50; ECF No. 15 at PageID.168. Because Plaintiffs are unlikely to prevail on the merits, their argument that it is in the public’s interest to avoid constitutional violations is without merit. Additionally, assuming the injunction only applies to B.O., the injunction would not serve the public interest. However, if a significant number of people sought injunctions, it could cause harm to the public interest. Therefore, this factor favors Defendants.

F.

At the end of Plaintiffs’ reply, they state

[I]f this Court does not grant the preliminary injunction and Defendants’ are allow[ed] to proceed, they will undoubtedly seek thereafter to dismiss on mootness grounds. After the unconstitutional acts are completed, there will seemingly not be available monetary damages due to qualified immunity and state sovereign immunity. By defeating this motion, Defendants will effectively avoid a merits decision. This should not be permitted.
ECF No. 21 at PageID.238.

The Court declines to address the question of mootness at this juncture. If Defendants do bring a mootness challenge, then the Court will consider the argument, as well as any possible defenses Plaintiffs might have.

IV.

Accordingly, **IT IS ORDERED** that Plaintiffs’ Motion for Preliminary Injunction, ECF No. 3, is **DENIED**. All four claims remain.

Dated: March 24, 2020

s/Thomas L. Ludington
THOMAS L. LUDINGTON
United States District Judge